UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,166	03/17/2004	James Robert Schwartz	9184M	4150
	7590 05/28/200 R & GAMBLE COMP		9184M EXA ARNOL ART UNIT 1616 MAIL DATE	INER
Global Legal Department - IP ARNOLD, ERNST V			ERNST V	
•	Sycamore Building - 4th Floor 299 East Sixth Street		ART UNIT	PAPER NUMBER
CINCINNATI,	OH 45202		1616	
			MAIL DATE	DELIVERY MODE
			05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/802,166	SCHWARTZ ET AL.			
		Examiner	Art Unit			
		ERNST V. ARNOLD	1616			
Period fo	The MAILING DATE of this communication apported in the policy of the plant in the plant i	pears on the cover sheet with the	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)	Responsive to communication(s) filed on <u>06 F</u>	ahruary 2009				
•		s action is non-final.				
3)	·—		osecution as to the merits is			
ت (۵	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
· ·	Claim(s) 1,3,4 and 7-27 is/are pending in the a	annlication				
•	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
· ·	6) Claim(s) 1,3,4 and 7-27 is/are rejected.					
-	Claim(s) is/are objected to. Claim(s) are subject to restriction and/o	or election requirement				
		or election requirement.				
Applicati	on Papers					
9)	The specification is objected to by the Examine	er.				
10)	10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)	11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority ι	ınder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
2) 🔲 Notic 3) 🔯 Infori	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>2/6/09</u> .	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	pate			

DETAILED ACTION

Claims 26 and 27 are new. Claims 2, and 4-6 have been cancelled. Claims 1, 3, and 7-27 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 2/6/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

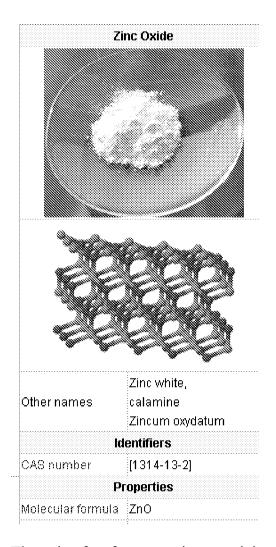
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7-13, and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151) as evidenced by the Wikipedia Zinc Oxide.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising form 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic detersive surfactant (about 5 to about 50% by weight) for a topical carrier (Page 8, lines 10-15 and Claim 1). The zinc salt can be but is not limited to, for example, zinc oxide (page 6, lines 1-6 and Claim 6). From Wikipedia, zinc oxide is shown to clearly have a layered crystal structure reproduced below for Applicant's benefit:

Art Unit: 1616



The ratio of surfactant to zinc containing layered material can be greater than or equal to 2 to 1. In this way, instant claims 1, 3, 4, 7 and 8 are anticipated. Since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1, 12 and 13. Please note that "relative zinc lability" is a made up in-house feature by Applicant. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-

Application/Control Number: 10/802,166

Art Unit: 1616

page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Page 4

Response to arguments:

Applicant asserts that zinc oxide is not a layered material. Respectfully, the Examiner cannot agree. Zinc oxide has layers just as graphite has layers. It is therefore a layered material. The instant specification on page 5, lines 3-10 and 29-30 provides some clarification of what may be a zinc containing layered material but is not intended to be limiting as to the broader scope of materials which fit this definition which could include zinc oxide.

Applicant asserts that the zinc oxide has a low intrinsic zinc lability as compared to basic zinc carbonate. However, this is only true with respect to the system as a whole as, for example, in an anionic surfactant system. In water, the zinc oxide and basic zinc carbonate have nearly the same (86.3 and 100%, respectively) relative zinc lability and the claim states: "wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%". The Examiner broadly interprets this limitation to be a property of the zinc layered material. In water, zinc oxide has a zinc lability of greater than 15% as shown by Applicant and thus meets the limitation of the claim. The claim language does not limit the zinc lability of the zinc containing layered material to compositions with surfactants with anionic functional groups.

Art Unit: 1616

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 8-13, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiese (US 5,227,156) as evidenced by the Wikipedia Zinc Oxide.

Wiese discloses compositions comprising up to about 40% surfactants (anionic, nonionic, amphoteric and zwitterionic); from about 0.1% to about 2% zinc pyrithione; from about 0.001% to about 1% of zinc oxide (claim 1). The evidence from Wikipedia zinc oxide is presented above and is hereby incorporated by reference. The ratio of surfactant to zinc containing layered material can be greater than or equal to 2 to 1. Since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1, 3, 4, 7, 8, 12 and 13. Wiese discloses that the pH control agents can be added such that the composition has a neutral to slightly acidic pH which anticipates instant claims 9-11. Wiese disclose in claim 9, a composition comprising a suspending agent (magnesium aluminum silicate/hydroxypropyl methyl cellulose (polymeric suspending agent) thus reading on instant claims 20 and 21.

Response to arguments:

Applicant asserts that zinc oxide is not a layered material. Respectfully, the Examiner cannot agree. Zinc oxide has layers just as graphite has layers. It is therefore a layered material.

Art Unit: 1616

The instant specification on page 5, lines 3-10 and 29-30 provides some clarification of what may be a zinc containing layered material but is not intended to be limiting as to the broader scope of materials which fit this definition which could include zinc oxide.

Applicant asserts that the zinc oxide has a low intrinsic zinc lability as compared to basic zinc carbonate. However, this is only true with respect to the system as a whole. In water, the zinc oxide and basic zinc carbonate have nearly the same (86.3 and 100%, respectively) relative zinc lability and the claim states: "wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%". The Examiner broadly interprets this limitation to be a property of the zinc layered material. In water, zinc oxide has a zinc lability of greater than 15% as shown by Applicant. The claim language does not limit the zinc lability of the zinc containing layered material to compositions with surfactants with anionic functional groups.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1616

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, and 7-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) in view of Iwai et al. (EP 1145707A1) or Bhat et al. (WO 96/25913).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art (MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Iwai et al. teach compositions for external use comprising: 0.01-20 wt% of a zinc compound, such as basic zinc carbonate; 0.01-20 wt% of a thiol compound; and an anionic surfactant (Claims 1, 2, 4, 6 and 7 and page 8 lines 4 and 46 bridging page 9 line 9, for example). It is the Examiner's position that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Iwai et al. teach adding cationic surfactants (page 9, lines 4-9). Iwai et al. teach adding thickeners (suspending agents) such as gelatin, guar gum and methyl cellulose (page 9, lines 55-58). Iwai et al. teach the addition of various oils (conditioning agents) to the composition (page 8, lines 5-45).

Art Unit: 1616

Bhat et al. teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is Zn₅(OH)₆(CO₃)₂ X H₂O where X varies between 0 and 4 (Page 6, lines 23-27). When X=0 then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

1. Gavin et al. do not expressly teach a composition comprising as the zinc salt basic zinc carbonate from about 0.001% to about 5% or the narrower range of about 0.1% to about 5% and as the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione from about 0.01% to about 5% or the narrower range of about 0.1% to about 2%. This deficiency in Gavin et al. is cured by the teachings of Iwai et al. or Bhat et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Gavin et al. comprising as the zinc salt basic

Art Unit: 1616

zinc carbonate from about 0.001% to about 5% or the narrower range of about 0.1% to about 5% and as the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione from about 0.01% to about 5% or the narrower range of about 0.1% to about 2%., as suggested by Iwai et al. or Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition but not specifically basic zinc carbonate and Iwai et al. or Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for external compositions. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

Art Unit: 1616

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that there is no motivation to combine the basic zinc carbonate in Iwai et al. and combine it with the zinc pyrithione of Gavin et al. Respectfully, the Examiner cannot agree. The materials are taught in the art for the same purpose and *In re Kerkhoven* establishes that is obvious to combine such composition in the absence of evidence to the contrary. There is no teaching away in the art not to select basic zinc carbonate and there is no evidence to the contrary.

Applicant asserts that the present invention has found the components and ratios that result in the specified lability. However, it appears that basic zinc carbonate is very zinc labile whether it is in water or in the presence of anionic surfactants (100% in water and 37% in simple surfactant system: page 31, lines 5-10 of the instant specification) and thus such a property is intrinsic to the material and not dependent on components and ratios. Applicant's assertions that the ratios of zinc component to surfactant are much higher in the cited art are not persuasive because the instant claims require a ratio of surfactant to zinc containing layered material of greater than or equal to 2 to 1. Anything greater than or equal to the ratio of 2 to 1 meets the

Art Unit: 1616

limitation. Gavin et al., for example, teach from 0.001 to about 10% of a zinc salt and an anionic detersive surfactant (about 5 to about 50% by weight) which can produce a composition with 20% anionic surfactant and 10% zinc salt which would be a ration of 2:1 and meet the instant limitation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3, 4, 7-17 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25 of copending Application No. 10/803126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses methods of treating microbial infections, fungal infections and dandruff

with a composition comprising from about 0.01% to about 5% of a polyvalent metal salt of pyrithione (zinc pyrithione) and from about 0.001% to about 10% of a zinc layered material basic zinc carbonate. The copending application teaches personal care compositions such as shampoo and soaps.

The copending application does not expressly disclose adding from about 10 to 50% of the total composition of anionic surfactants to provide a ratio of surfactant to zinc layered material of greater than or equal to 2:1, pH greater than 6.5 or from about 6.8 to about 9.5 and relative zinc lability.

However, the open language of the copending application allows for the addition of anionic functional group surfactants to shampoo and soaps compositions and it is within the skill of one of ordinary skill in the art to optimize the amount of surfactant in the composition to produce the desired result and produce the instantly claimed ratio. Measurement of pH is routine in solution formulation and merely judicious selection of components to arrive at the instantly claimed pH. Relative zinc lability is intrinsic in the basic zinc carbonate.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant has filed a terminal disclaimer which has not as yet been approved. Until it is approved the Examiner must maintain the rejection.

Art Unit: 1616

2. Claims 1, 3, 7-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-12, 16-32, and 34-39 of copending Application No. 11/602770. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions, shampoo and methods of treating dandruff with an effective amount of a particulate zinc material (such as basic zinc carbonate); 0.01-5% zinc pyrithione, 1-50% anionic surfactants. The copending application discloses cationic deposition polymers, conditioning agents, suspending agents, pH ranges, relative zinc labilities and various surfactants.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserts that the instant invention is not directed to a dispersed gel network phase and that the copending application does not require a zinc lability greater than about 15% for a zinc containing layered material. Respectfully, the Examiner cannot agree because the

Art Unit: 1616

instant applicant uses open language and can include other ingredients to make a gel network and the zinc lability is an intrinsic property to the zinc material.

3. Claims 1, 3, 7-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 13-130, 35 and 37-40 of copending Application No. 11/890684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff comprising a particulate zinc material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 1% to about 50% anionic surfactant; pH; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserts that the instant invention is not drawn to a composition containing water soluble or dispersible, cationic, non-crosslinked conditioning homopolymer having a cationic charge density. However, the instant open language allows for additional ingredients.

Furthermore, the copending application positively recites the same components as instantly claimed including anionic surfactants (claim 17). Applicant's arguments are not persuasive.

4. Claims 1, 3, and 7-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff, fungal and microbial infections comprising a 0.001% to about 10% zinc containing material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 5% to about 50% anionic surfactant; pH is greater than about 7; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserts that the instant application is directed to zinc containing layered materials and not zinc materials with an aqueous solubility of less than about 25% by weight at

Art Unit: 1616

25 C. However, the copending application recites basic zinc carbonate which intrinsically meets the instant limitations. Applicant's arguments are not persuasive and the rejection is maintained.

5. Claims 1, 3, 7, 8, 12, 13, and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of copending Application No. 12/029150 in view of Gavin et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions comprising a zinc containing layered material (basic zinc carbonate); anionic surfactant; and relative zinc lability. The copending application does not expressly teach adding zinc pyrithione or the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

Gavin et al. teach zinc pyrithione in personal care compositions for treating microbes as discussed above.

However, the open language of the copending application allows for the addition of other ingredients such as zinc pyrithione as taught by Gavin et al. With respect to the amounts of ingredients, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Art Unit: 1616

Applicant asserts that the instant application is not drawn to a personal care method but rather a personal care composition. While this is correct, one must be in possession of the composition in order to practice the method of '150 application. The Examiner notes for the record that the method claims in '150 were not restricted out from the instant application. It is also correct that the '150 does not require zinc pyrithione but the open claim language does not exclude its presence either and the art teaches zinc pyrithione in personal care compositions for treating microbes.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 6:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/ Examiner, Art Unit 1616